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| 10/060,793 | 01/30/2002 | Pradip Mukerji | 6884.US.01 | 8246 |

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| EXAMINER | |
|---|---|
| MCELWAIN, ELIZABETH F | |
| **ART UNIT** | **PAPER NUMBER** |
| 1638 | |

DATE MAILED: 12/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/060,793 | MUKERJI ET AL. | |
| | Examiner | Art Unit | |
| | Elizabeth F. McElwain | 1638 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *6-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 5* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/23/04;6/6/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

The amendment filed September 26, 2005 has been entered.

Claims 1-3 are currently amended.

### *Election/Restrictions*

1. Applicant's election of Group I, claims 1-5 and SEQ ID NO: 25 and 26 in the reply filed on September 26, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### *Specification*

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to any isolated nucleic acid encoding a desaturase that

has at least 50% sequence identity to SEQ ID NO: 25, or any isolated nucleic acid sequence or fragment thereof comprising or complementary to a nucleotide sequence having at least 50% sequence identity to SEQ ID NO: 25. However, the specification only teaches SEQ ID NO: 25 encoding SEQ ID NO: 26 that has desaturase activity. The specification does not teach the structural features required for desaturase activity. In addition, the prior art teaches only one desaturase coding sequence that falls within the scope of the claims, but it is unclear which areas of sequence similarity are required for said activity. In the present case, the one example of a desaturase coding sequence is not sufficient to describe the claimed genus.

"A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." In addition, "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention". See *University of California v. Eli Lilly and Co.,* 119 F. 3d 1559; 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

4. Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid of SEQ ID NO: 25 encoding SEQ ID NO: 26, does not reasonably provide enablement for any isolated nucleic acid encoding a desaturase that has at least 50% sequence identity to SEQ ID NO: 25, or any isolated nucleic acid

sequence or fragment thereof comprising or complementary to a nucleotide sequence having at least 50% sequence identity to SEQ ID NO: 25. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Sequence homology is not sufficient to predict function of encoded sequences. See the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and "overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar functions" (the last sentence of the first paragraph of page 248). Doerks also teaches homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph). In addition, Smith et al (Nature Biotechnology 15:1222-1223, November 1997) teach "there are numerous cases in which proteins of very different functions are homologous" (page 1222, the first sentence of the last paragraph). Also, Brenner (TIG 15, 4:132-133, April 1999) discusses the problem of inferring function from homology, stating "most homologs must have different molecular and cellular functions" (see the second full paragraph of the second column of page 132, for example). Furthermore, Borks (TIG 12, 10:425-427, October 1996) teaches numerous problems with the sequence databases that can result in the misinterpretation of sequence data.

More specifically, identification of related sequences that will encode enzymes having a particular activity is particularly problematic in the enzymes involved in modifying fatty acids, and cannot be determined merely by similarity of DNA or amino acid sequences. Van de Loo et al teach that sequences encoding fatty acid hydroxylase activity are highly similar to other

sequences that do not encode a hydroxylase, but instead encode a fatty acyl desaturase (see the abstract, at least). In fact, Broun et al teach that a change in only four amino acids will convert a desaturase gene to a hydroxylase gene (see the abstract, at least). Thus, if sequences are identified only by similarity to other sequences that are known to encode desaturase activity, one cannot conclude that these other sequences also encode enzymes having desaturase activity.

Therefore, given the unpredictability of identifying sequences that desaturase activity; the lack of guidance in the specification for identifying and characterizing other sequences that exhibit desaturase activity and have at least 50% sequence identity to SEQ ID NO: 25; the lack of working examples of other similar coding sequences, and the lack of working examples of similar sequences that encode proteins having the same activity; and given the breadth of the claims, which encompass any isolated nucleic acid sequence or fragment thereof comprising or complementary to a nucleotide sequence having at least 50% sequence identity to SEQ ID NO: 2; it would require undue experimentation by one skilled in the art to make and use the invention as broadly claimed.

### *Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 2, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Thomas et al (US Patent 5,614,393).

7. The claims are drawn to any isolated nucleic acid encoding a desaturase that has at least 50% sequence identity to SEQ ID NO: 25, or any isolated nucleic acid sequence or fragment thereof comprising or complementary to a nucleotide sequence having at least 50% sequence identity to SEQ ID NO: 25, wherein a fragment could be as small as one nucleotide, and the organism from which it is derived would not confer a patentable distinction to the claimed nucleic acid.

8. Thomas et al teach an isolated nucleic acid encoding a desaturase, and a fragment thereof anticipates the claims.

9. Claims 2, 4 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Roessler et al (US 20050112719 A1).

10. The claims are drawn to any isolated nucleic acid encoding a desaturase that has at least 50% sequence identity to SEQ ID NO: 25, or any isolated nucleic acid sequence or fragment thereof comprising or complementary to a nucleotide sequence having at least 50% sequence identity to SEQ ID NO: 25, wherein a fragment could be as small as one nucleotide, and the organism from which it is derived would not confer a patentable distinction to the claimed nucleic acid.

11. Roessler et al teach an isolated nucleic acid encoding a desaturase and having a local similarity of 52.2% from nucleotides 203 to 1016. See SEQ ID NO: 16, which is identified as an omega-3 fatty acid desaturase at [0028].

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth F. McElwain, Ph.D.
Primary Examiner
Art Unit 1638

EFM